# HEALTH AND SOCIAL CARE RESEARCH POLICY v3.0

## 1. INTRODUCTION

***Health and social care research*** is research that falls under the UK Policy Framework for Health and Social Care Research. This means research which is concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken within social care agencies. It includes clinical and non-clinical research undertaken within the health and social care systems that might have an impact on the quality of those services.

### 1.1 Purpose

This policy details the expectations of Keele University for its researchers' undertaking health and social care research under the UK Policy Framework for Health and Social Care Research. A key objective of health and social care research at Keele is to improve the health and welfare of individuals with health conditions by producing world-leading research that impacts across the field, ranging from the laboratory investigation of cellular mechanisms to developing and testing innovative clinical interventions. Keele is committed to supporting and conducting research to the standards set by the UK Policy Framework for Health and Social Care Research.

### 1.2 Scope

This Policy applies to all Keele University staff members, Keele University honorary contract holders and others within Keele University who are actively involved in health and social care research. By reading this document, all persons conducting research in this setting should be aware of what is expected of them.

Health and social care research (and, in particular, clinical trials) is governed by regulatory requirements, internationally accepted standards and governance frameworks, all with the ultimate aim to ensure participant safety and data quality. Any researcher involved in health and social care research must identify, familiarise themselves with and adhere to any applicable regulations, standards and governance frameworks.

It is the policy of Keele University that all applicable legislative and regulatory governance frameworks for health and social are research are adhered to. Keele University has implemented a Quality Management System for health and social care research (the HSCR QMS). Its development and maintenance is informed by (but not limited to) the following regulations, standards and governance frameworks (and subsequent updates / amendments to these) which will be adhered to in the conduct of health and social care research:

- UK Policy Framework for Health and Social Care Research (v3.3 07-Nov-2017) ¨
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (UK SI 2004 No. 1031)

- The Medical Devices Regulations 2002 (UK SI 2002 No. 618)
- Data Protection Act 2018
- Mental Capacity Act 2005
- Human Tissue Act 2004
- Human Tissue Authority (HTA) Codes of Practice
- International Council on Harmonisation (ICH): Guidelines for Good Clinical Practice (GCP) E6(R2)
- European Medical Agency - Reflection paper for laboratories that perform the analyses or evaluation of clinical trial samples (PDF - 136 KB).

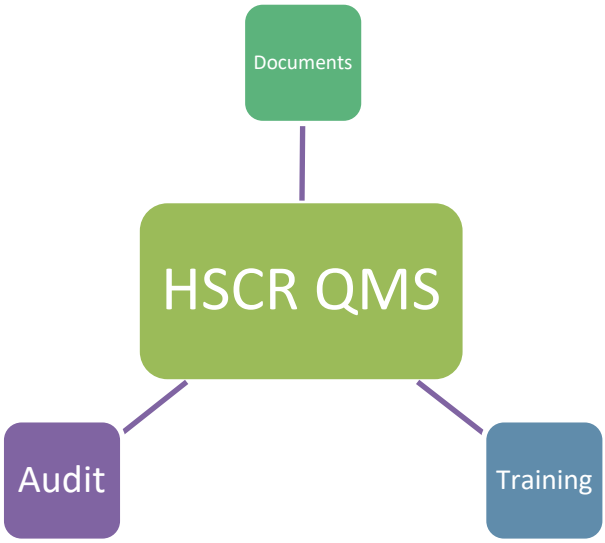
The HSCR QMS is a suite of documented procedures, training provision and quality control/quality assurance processes, which ensures legislative compliance across all aspects of health and social care research managed and conducted by Keele University as well as meeting the expectations of funders, collaborators and participants.

The HSCR QMS serves as a training tool so that any staff member following it can be assured that the safety and wellbeing of participants are protected, data integrity is maintained and that the research is conducted in compliance with Good Clinical Practice, regulations, national standards and University policies.

## 2. POLICY

### 2.1 Quality Management and Compliance

The **Project Assurance Research Governance** Team (Research Governance; see section 6.4) is responsible for the management and development of the Keele Health and Social Care Research Quality Management System (HSCR QMS) covering key processes that must be followed when conducting health and social care research.




The **Health Research Oversight Committee** (HROC; also see section 6.3) have oversight of this Quality Management System.

University research teams and units may have their own Standard Operating Procedures (SOPs), or equivalent, covering local activities. If local procedures are in place, these must meet the minimum standards set out within the HSCR QMS Standard Operating Procedures and a local staff member (or group) should take responsibility for ensuring that local processes meet and comply with the standards required by the Keele HSCR QMS and ensure that local procedures remain compliant with wider University requirements.

Keele University maintains the HSCR QMS as a suite of policies, procedures and guidelines to ensure standards and legislative requirements are met. This section provides an overview of these standards as relevant to Health and Social Care research. This overview must be read in conjunction with the other documents within the HSCR QMS. It does not replace these requirements and the specific policies referred to will provide more detailed information not contained in this overarching policy.

Where necessary the HSCR QMS provides additional detail of the standards expected. The University will assess, identify and document requirements on a research specific basis through quality control mechanisms and risk assessments.

### 2.1.1 Training

Any staff involved in health and social care research must be appropriately qualified by education, training and experience to take on their respective task(s) in the research. Any relevant training or education must be documented, and readily available e.g. for quality review.

Individuals who are involved in the day to day (site) management of a CTIMP (e.g. chief investigator, research nurse, trial manager / coordinator) are required to have completed accredited Good Clinical Practice training (recognised by the MHRA). In addition, these individuals must ensure (and be able to evidence) they stay up to date with their knowledge of Good Clinical Practice and applicable regulations, for example through completing Good Clinical Practice refresher courses approximately every 3 years. For all other research (non-CTIMPs) it is recommended that staff have completed Good Clinical Practice training relevant to their role.

### 2.1.2 Participant Safety

For health and social care research Keele University, as sponsor, via Research Governance (delegated to Keele Clinical Trials Unit where applicable) will take on the role of ensuring processes are in place such that:

- Serious Adverse Events (SAEs) are reported in accordance with the regulations, ethical approval requirements and manufacturer requirements (when required)
- Protocols include clear mechanisms for safety reporting, relevant safety sections around interventions and/or a safety plan where the research requires it
- Where necessary, studies have appropriate Data Monitoring Committees
- The need for urgent safety measures are recognised and implemented
- Appropriate actions are taken for serious breaches of the protocol and / or GCP

Additionally, for CTIMPS:

- That safety issues relating to a specific investigational medicinal product are reported to any other trial team of a University-sponsored trial using the same investigational medicinal product

- Mechanisms for acting on safety signals, both clinical and non-clinical, are in place where required

- There are processes in place to ensure the accuracy, quality and timely submission of development safety update reports (where applicable)

### 2.1.3 Data Protection

All staff must ensure they are aware of Keele University policies for information governance and their responsibilities to work in accordance with the Data Protection Act and UK General Data Protection Regulation (UK GDPR) and have completed an appropriate level of training in Information Governance. Keele University is registered with the Information Commissioner's office (Registration Number: Z5571818) for the purposes of processing personal information for research.

Keele University will process personal information for research without participant consent only where the Confidentiality Advisory Group of the Health Research Authority has considered a proposal meets the necessary requirements, is fully supported by the Confidentiality Advisory Group and the processing has been reviewed by the School Research Director, reported to the Data Protection Officer and an Information Guardian has been identified.

### 2.1.4 Data Management

Keele University staff must ensure that all research data is stored appropriately for their research. The data should be secure and protected from inadvertent use. The data should also be resilient and backed up to prevent loss in the event of a disaster, and data management processes should ensure protection of the integrity of the research data.

All staff members will have access to University file servers where a fixed amount of data can be stored. These data are backed up on a daily basis. Data retention durations are in accordance with Keele University **Records Retention Schedule**.

### 2.1.5 Document storage and archiving

Universities have a legal responsibility to maintain records safely and securely in accordance with the Data Protection Act 2018. Staff are responsible for making sure that all records are periodically and routinely appraised to determine what can be transferred to Keele University archive sites.

Research-related documentation is archived in accordance with the University's Record Retention Schedule or otherwise in accordance with the applicable regulations or instruction from the sponsor.

### 2.1.6 Quality Assurance

Keele University undertakes audit of health and social care research in accordance with its Audit Programme. This audit programme is designed to help minimise the risk of poor quality research, adverse incidents, research misconduct and fraud. Findings are resolved primarily by research teams and are reported to Keele University's committee structure (see Figure 1) and escalated in accordance with risk.

Individual Faculties may instigate additional audit programmes, for example the Clinical Trials Unit, which will also inform the Research Governance audit programme.

Keele University may undertake audit of partner sites, vendors or overseas bodies conducting activity for Keele University sponsored research.

### 2.1.7 External Review

Keele University may seek external review or consultation of any aspect of the Keele Research Health and Social Care Quality Management System, including this policy. Review bodies may include but are not limited to other UK Universities, NHS Trusts and relevant regulatory or advisory bodies.

### 2.1.8 Sponsorship of Health and Social Care Research

Keele University is prepared to act as sponsor for research under the **UK Policy Framework for Health and Social Care Research** and the **Medicines for Human Use (Clinical Trials) Regulations**.

As Sponsor, Keele University takes responsibility for the initiation, management and financing (or arranging the financing) of the research. In order to undertake this role, Keele University must therefore satisfy itself that the research meets the relevant standards and ensure that arrangements are put and kept in place for management, monitoring and reporting. The following principles apply:

- Any Clinical Trial of an Investigational Medicinal Product (CTIMP) sponsored by Keele University must be managed IN FULL by a UK CRC Registered Clinical Trials Unit (UKCRC).
- Sponsorship in principle can be assumed for the purpose of funding applications if the University's Criteria for Sponsorship (see appendix 1) is met in full and the research project is NOT a CTIMP or regulated Devices trial
- Full sponsorship cannot be presumed, and confirmation of sponsorship must be obtained prior to submission for NHS Research Ethics Committee (REC) or regulatory authority review
- In the case of research projects being undertaken by a student as part/fulfilment of an academic qualification, the UK Policy Framework for Health and Social Care Research and HRA guidance on who should be Chief Investigator (CI) should be followed, with the student's University-employed supervisor usually undertaking the role of CI
- The University does not permit its members of staff or students to assume the role of sponsor on a personal basis
- The University's Criteria for Sponsorship should be met (see Appendix 1)
- Sponsorship will only be considered for research projects that make an application in accordance with the process laid down within the HSCR QMS

The Research Governance Team is responsible for making the initial assessment for sponsorship through a triage process outlined in the HSCR QMS.

Keele University will not take on a joint or co-sponsorship role, as these arrangements do not allow for clear division and delivery of responsibilities.

If Keele University agrees to act as sponsor, full sponsorship will be confirmed in writing, with a clear documented audit trail where conditions of sponsorship have been set and (where necessary) fulfilled.

Only individuals listed in the **Delegation of Sponsor Signatories** document are authorised to confirm sponsorship in principle and full sponsorship. No other individuals have the authority to do so.

For Keele University sponsored studies, it will confirm approval of protocols by authorisation of IRAS forms for submission of research documentation to the regulatory body, Health Research Authority (HRA) and/or NHS research ethics committee (REC). The sponsor must be notified of all amendments to the protocol, both substantial and non-substantial. Review and authorisation of amendments by the sponsor will act as the confirmation that the sponsor confirms approval of the amended protocol and / or associated research documents.

### 2.1.9 Withdrawal of Sponsorship

Where in the view of the Head of Project Assurance, circumstances represent an inability for Keele University to execute its responsibilities fully as sponsor or an unacceptable risk to Keele University or research participants, they may recommend action to the Director of Research Strategy Delivery (or their delegate). The Director of Research Strategy Delivery (or their delegate), without limitation, may mandate the temporary halt, suspension or termination of the research or seek to transfer sponsorship to another organisation or any other appropriate action to protect participants or the University.

### 2.1.10 Delegation of Sponsor Functions

As sponsor, Keele University may formally delegate one or more of the elements of sponsorship, but it remains accountable for all aspects of sponsorship whether delegated or not.

Where Keele University accepts the role as sponsor, the Chief Investigator will confirm their acceptance of Chief Investigator responsibilities and sponsor duties delegated to the Chief Investigator via a **Delegation of Sponsor Functions Agreement**. It is expected that sponsor functions delegated to the Chief Investigator may be further delegated to suitably qualified / trained staff members within Keele University but may also be delegated externally where appropriate. All sub-delegations will be recorded in writing.

Where another institution is to take on a significant area of operational duties for a research project this will be by way of formal delegation of sponsor functions through a legally-binding contract or similar signed on behalf of the University.

Where a United Kingdom Clinical Research Collaboration (UKCRC) registered Clinical Trials Unit takes on the management of the research project, it is expected that the agreement between Keele University and the external Clinical Trials Unit will clearly explain the following -

- A clear description of the division of responsibilities and duties between the Sponsor, Chief Investigator, and the Clinical Trials Unit
- A clear agreement as to which organisation's Quality Management System will be adhered to. Where an external Quality Management System is to be used, the Research Governance team and the Chief Investigator must satisfy themselves that the proposed Quality Management System meets (or exceeds) the standards required by Keele University as described in its HSCR QMS. This assessment will be documented and kept on file in the (Study) Master File by the Chief Investigator (or their delegate) and by the Research Governance team in the Sponsor File.

  The Chief Investigator and their team are responsible for overseeing that the terms in the contractual agreement are met.

## 2.2 Keele University as a Host

Keele University may act as a research host where it takes on the role of managing and coordinating health and social care research or conducting discrete bodies of work in the analysis of research material on behalf of or in collaboration with an external sponsor.

Examples, though not exhaustive, would be providing the services of its Clinical Trials Unit, undertaking one or more individual tasks such as monitoring, pharmacovigilance, Investigational Medicinal Product supply, database development, data management and statistical expertise.

A contract must be in place at the start of the research to describe what tasks or activities are delegated to Keele University by the Sponsor. Where Keele University undertakes specific tasks, it is responsible for ensuring those tasks are conducted as expected and in line with the relevant Quality Management System. The Academic Lead at Keele is responsible for ensuring that the standard of procedures that they are required to work to (where not Keele's) meet or exceed those as described within Keele's QMS. The Academic Lead (and the Keele Clinical Trials Unit if involved) and the Faculty operations teams are responsible for oversight of research activity hosted at Keele University, and that the terms in the contractual agreement are met.

### 2.2.1 Keele University as a Research Site

A research site is defined by the HRA as an organisation or unit responsible for conducting any of the research procedures at a particular locality. This is limited to research activity which has direct interaction with research participants.

Keele University will not normally act as a non-NHS site for Clinical Trials of Investigational Medicinal Products, device trials or other interventional trials altering patient care. No participants will receive interventions for clinical trials requiring clinical trial authorisations on Keele University premises.

### 2.2.2 Global Health and Social Care Research

Where a health and social care research project is to be delivered outside of the UK and Keele are the lead organisation for the research, the Research Governance team will assess the most appropriate sponsorship arrangements. All global health research partners and projects must be subject to the University's due diligence process. Actions relating to the outcomes of the due diligence and risk assessment process will be overseen by the Director of Research Strategy Delivery or their delegate. Where required, issues may be escalated to the Health Research Oversight Committee (HROC).

### 2.2.3 Insurance

Insurance is required to cover all the University's liabilities in relation to its research activity. The University has insurance policies in place to cover Professional Indemnity, Clinical Trials Insurance and Public Liability Insurance, which together provide cover for much of the University's research portfolio. However, there are some notable exceptions to this, where specific projects may need to be referred to the University's insurers to confirm cover, or further, where additional insurance may be required. This includes, for example, research taking place in overseas sites where local legislation may prevent the use of our UK policy and require locally sourced insurance cover or relating to particular groups of patients.

The University will not normally pay for additional insurance costs and research may not be able to proceed unless alternative funding for this insurance is found. It is the responsibility of the Chief

Investigator to ensure that there is appropriate funding to cover all the costs of the research including insurance costs.

### 2.2.4 Research Oversight of Sponsored Research

Keele University in its role as sponsor and host for health and social care research has set up an infrastructure for maintaining appropriate oversight and uses a number of committees, groups and individuals that are fully committed to research oversight.

## 2.3 Senate

The Senate is the academic governing body of Keele University. Its responsibility is to direct academic policy in relation to teaching and research, and to assure itself that Keele University's academic standards are properly observed.

## 2.4 University Research Committee

The Research Committee is one of the Senate committees and is responsible for all matters concerning the management of, and support for, Keele University research.

## 2.5 Health Research Oversight Committee (HROC)

The Health Research Oversight Committee is coordinated by Research Governance and the minutes/reports are made available to the Research Committee. The Terms of Reference include (but are not limited to):

- Oversight of sponsorship arrangements for health and social care research
- Oversight of the development, management and scope of the HSCR Quality Management System documentation
- Oversight of Keele University's health and social care research audit programme, its delivery, findings, their resolution and escalation
- Review of outcomes of external audits and inspections of the University's portfolio of health and social care research and to monitor the implementation of agreed audit or inspection recommendations
- Oversight of the development and delivery of Keele University training in relation to the roles and responsibilities undertaken by University staff for health and social care research
- Ensuring that all health and social care research is carried out in line with applicable legislation and best practice
- Provision of expert input on health and social care management processes
- Assessment of situations requiring Keele University to consider its role as sponsor

## 2.6 Project Assurance Research Governance

Research Governance is responsible for the day-to-day management of Keele University's sponsor oversight systems.

Research Governance coordinates:

- Sponsor level quality control and quality assurance functions, including sponsor review of research documentation.

- Development and management of the University's Health and Social Care Research Quality Management System.
- Research audits across Keele University, focussing on the controls that Faculties have put in place to ensure appropriate governance, risk management, quality and adherence to regulations, the Quality Management System, and University policies and processes.
- The University's training in relation to health and social care research where not provided on a local level.
- Co-ordination of external inspections, assessments or visits including resolution and escalation as necessary.

### 2.7 Keele Clinical Trials Unit (Keele CTU)

Keele Clinical Trials Unit reports into the Faculty of Medicine and Health Sciences at Keele University. Keele Clinical Trials Unit holds full registration status with the UK Clinical Research Collaboration (UKCRC) Network (Clinical Trials Unit registration number 36) and receives funding from the National Institute for Health Research core funding and research grant income. Keele CTU has processes in place to support the development of new health and social care research studies, including clinical trials, and a process of requesting Keele CTU collaboration prior to research grant submission.

Where research has been adopted by Keele CTU, the CTU holds accountability for the day to day management of the research delegated to it by the Sponsor. Any risks identified within the CTU are escalated to Clinical Trials Unit Operations group, the Clinical Trials Unit Leadership group, the Faculty Research Committee, Health Research Oversight Committee and/or Sponsor (as deemed necessary).

Any risks identified within the CTU are escalated through CTU operational pathways to the host Faculty and ultimately the University Research Committee.

The CTU manages activities relating to United Kingdom Clinical Research Collaborative registration of Keele Clinical Trials Unit as they relate to the Quality Management System.

### 2.8 Organogram of Keele University oversight in Health and Social Care Research

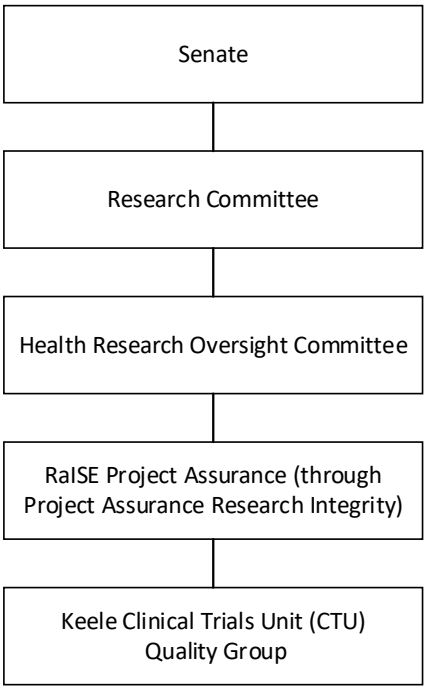


**Figure 1 - Overview of Research Governance Structure**

## 3. ROLES AND RESPONSIBILITIES

### 3.1 Chief Investigator

The **Chief Investigator** is the researcher who takes primary responsibility for the conduct of the research. The HSCR QMS recognises only the Chief Investigator in this role, this role cannot be shared and must be held by an individual. Co-Chief Investigators are not supported in the HSCR QMS.

The University follows the guidance of the Health Research Authority (HRA) when agreeing who can be the Chief Investigator for a research project. A researcher must be qualified by education, training and experience and have a substantive contract with Keele University to take on the role of Chief Investigator. By doing so, they take on responsibilities as assigned to the Chief Investigator in the UK Policy Framework for Health and Social Care Research.

For a Clinical Trial of an Investigational Medicinal Product, the Chief Investigator must also be an **authorised, registered health professional (specifically either a doctor, dentist or pharmacist),** and the Chief Investigator takes on the Chief Investigator responsibilities as described in the Medicines for Human Use (Clinical Trials) Regulations. Keele University has developed a 'Delegation of Sponsor Functions Agreement' which summarises these responsibilities. The Chief Investigator must sign this declaration, thereby confirming they will take on the responsibilities assigned to them.

Where the Chief Investigator plans to leave the employment of Keele University, or take a period of prolonged absence, the following options are available:

- Transfer sponsorship of the research to the Chief Investigator's future employer, with their consent
- Retain sponsorship with contractual agreement with the Chief Investigator's future employer
- Retain sponsorship and appoint an alternative Chief Investigator based at Keele University
- Early termination of the research

The most appropriate option will be recommended by the Head of Project Assurance and ratified by the Director of Research Strategy Delivery (or their delegate).

Where the research is externally sponsored, the Chief Investigator should inform Research Governance of their role in the research.

#### 3.1.1 The Principal Investigator, Local Collaborator or Associate Investigator

A Principal Investigator is a person responsible for the conduct of research at a research site. The Principal Investigator may take on the responsibility individually or acting as a leader of multiple departments within the site. For a Clinical Trial of an Investigational Medicinal Product, a principal investigator at a clinical site must be an authorised, registered health professional.

Where the activities at the site are minimal and the Chief Investigator will undertake most activities, a Principal Investigator may not be required but a Local Collaborator based at the site must be identified. The **Local Collaborator** is defined as a person undertaking certain types of straightforward research procedure, not requiring the appointment of a Principal Investigator. Local collaborators at NHS sites must seek NHS permission. This will usually be the individual with whom the Chief Investigator has negotiated access to the site or the head of the department where the research will take place.

Members of Keele staff tasked with leading for discrete activities under a Keele Chief Investigator may also be named as an **Associate Investigator** within the research team. Examples include but are not limited to Associate Investigator for laboratory analysis or Associate Investigator for a clinical trial.

### 3.1.2 The Grant Holder(s)

Normally, the principal grant holder for the research will be expected to act as Chief Investigator. However, where the principal grant holder is not appropriately qualified to act as Chief Investigator (e.g. member of the CTIMP team who is not a doctor, dentist or pharmacist) then an appropriately qualified individual must be identified to act as Chief Investigator.

### 3.1.3 Other Research Staff

Any researchers conducting activity within NHS bodies or other non-Keele University sites may require access approval prior to the activity taking place.

Keele University supports the Department of Health's Research Passport as the means of undertaking necessary pre-engagement checks and manage the receipt of letters of access or honorary contracts to cover activity within NHS bodies.

Any researcher requiring a letter of access or an honorary contract at an NHS site is responsible for following the Research Passport process and complying with the limitations of any letter of access or honorary contract while conducting research.

Keele University will facilitate sharing of information about staff members through the appropriate channels outlined in the Research Passport resource pack and maintain up-to-date records of researchers conducting research activity external to Keele University.

## 4. RELATED POLICIES AND PROCEDURES

The University's Health and Social Care Research Quality Manual is extensive and is hosted on the Research and Innovation Hub to enable easy access by all staff. This can be found at

Health and Social Care Research at Keele University (sharepoint.com)

## 5. REVIEW, APPROVAL & PUBLICATION

Once approved by the University's Research Committee, the latest version of this policy will be found at https://www.keele.ac.uk/policyzone/

Any superseded versions of this document need to be promptly withdrawn from use.

## 6. ANNEXES

Annexe 1: Criteria for sponsorship of health and social care research

## 7. DOCUMENT CONTROL INFORMATION

| | |
|---|---|
| **Document Name** | Health and Social Care Research Policy |
| **Owner** | Director of Research Strategy Delivery |
| **Version Number** | 3.0 |
| **Equality Analysis Form Submission Date** | [Decision from Equality Analysis and form submission date] |
| **Approval Date** | 13/03/2024 |
| **Approved By** | Senate |
| **Date of Commencement** | 13/03/2024 |

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| **Date of Last Review** | 13/03/2024 |
| **Date for Next Review** | 13/03/2027 |
| **Related University Policy Documents** | [List all applicable] |
| *For Office Use – Keywords for search function* | |

## Annexe 1 Criteria for Keele University Sponsorship of Health and Social Care Research

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|---|---|
| **Chief Investigator (CI) and Study Management (all research)** | |
| If a member of staff, the CI must:<br>➢ be substantively employed by Keele University ***or***<br>➢ have an honorary academic contract (**not title**) with Keele University **and** (usually) be employed by a recognised Keele Partner Organisation ***or***<br>➢ (for research other than CTIMPs only) have an honorary academic contract (**not title)** with Keele University **and** the research must align with the research strategy of the relevant Faculty | |
| For student research, the UK Policy Framework for Health and Social Care Research and HRA guidance on who should be CI will be followed | |
| The CI must confirm that they will accept delegated functions from the Sponsor through the ***Delegation of Sponsorship Functions Agreement*** (***TEM03*** for CTIMPs or ***TEM77*** for all other studies) | |
| **Financing and Resources** | |
| Where funding is required,<br>➢ The research must have been costed in accordance with Keele University Research and Innovation Support Enhancement (RaISE) procedures.<br>➢ There must be an assessment that sufficient institutional infrastructure and resource to support the research are available (RaISE approval process).<br>➢ The research should be funded through a competitive funding stream where applicable. Where this is not the case, the research must have received adequate peer review | |
| For unfunded research,<br>➢ There must be an assessment by the CI and / or supervisory team (for student research) that sufficient institutional infrastructure and resource to support the research are available, as confirmed by the appropriate Faculty Business Manager / School Manager. This assessment must be in accordance with School / Faculty requirements.<br>➢ The research must have received adequate Peer Review | |